



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,071	06/25/2004	Toyoaki Ishikura	40072-0009	7307

26633 7590 12/12/2005

HELLER EHRMAN WHITE & MCAULIFFE LLP
1717 RHODE ISLAND AVE, NW
WASHINGTON, DC 20036-3001

EXAMINER

KIFLE, BRUCK

ART UNIT	PAPER NUMBER
----------	--------------

1624

DATE MAILED: 12/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Art Unit: 1624

Applicant's amendments and remarks filed 11/08/05 have been received and reviewed.

Claims 1-3, 5-10, 12 and 14-19 are now pending in this application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5-10, 12 and 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohtsuka et al. (US 6,372,735). The reference teaches the compound of Example 20 (col. 42, line 15 to col. 43, line 34). The claims differ by requiring the amorphous compound over the prior art crystals. Applicants state that the amorphous compound exhibits improved solubility over the prior art crystals.

However, it is known that amorphous pharmaceuticals are more soluble than their crystalline counterparts. See Hancock et al. (Pharmaceutical Research, Vol. 17, No. 4, 2000) which states:

"Amorphous pharmaceuticals are markedly more soluble than their crystalline counterparts, however, their experimental solubility advantage is typically less than that predicted from simple thermodynamic considerations. This appears to be the result of difficulties in measuring the true equilibrium solubility of amorphous materials. Thermodynamic predictions can provide a useful indication of the theoretical maximum solubility advantage for amorphous pharmaceuticals and an estimate of the driving force for their initial dissolution. Based on a comparison with polymorphic crystal forms of drug compounds the clinical relevance of solubility increases for amorphous drug forms is likely to be significant, even in systems which are only partially amorphous.

Therefore, the increased solubility is expected.

Art Unit: 1624

One skilled in the art would, thus, be motivated to convert crystalline pharmaceuticals into their amorphous counterparts with the expectation of achieving higher solubility. The process of spray-drying to yield amorphous compounds is known.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle, Ph.D. whose telephone number is 571-272-0668. The examiner can normally be reached Tuesdays to Fridays between 8:30 AM and 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bruck Kifle, Ph.D.
Primary Examiner
Art Unit 1624

BK
December 7, 2005